

**UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY**

\_\_\_\_\_, Individually and on behalf of all  
others similarly situated,

Plaintiff,

v.

ROCHE HOLDING AG, SEVERIN SCHWAN,  
and ALAN HIPPE,

Defendants.

Case No.

**CLASS ACTION COMPLAINT FOR  
VIOLATION OF THE FEDERAL  
SECURITIES LAWS**

**JURY TRIAL DEMANDED**

Plaintiff \_\_\_\_\_ (“Plaintiff”), individually and on behalf of all other persons similarly situated, by Plaintiff’s undersigned attorneys, for Plaintiff’s complaint against Defendants (defined below), alleges the following based upon personal knowledge as to Plaintiff and Plaintiff’s own acts, and information and belief as to all other matters, based upon, inter alia, the investigation conducted by and through Plaintiff’s attorneys, which included, among other things, a review of the defendants’ public documents, conference calls and announcements made by defendants, United States Securities and Exchange Commission (“SEC”) filings, wire and press releases published by and regarding Roche Holding AG (“Roche” or the “Company”), analysts’ reports and advisories about the Company, and information readily obtainable on the Internet. Plaintiff believes that substantial evidentiary

support will exist for the allegations set forth herein after a reasonable opportunity for discovery.

### **NATURE OF THE ACTION**

1. This is a federal securities class action on behalf of a class consisting of all persons and entities, other than Defendants, who purchased or otherwise acquired the publicly traded securities of Roche from March 2, 2017 through June 5, 2017, inclusive (the “Class Period”). Plaintiff seeks to recover compensable damages caused by Defendants’ violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “Exchange Act”) and Rule 10b-5 promulgated thereunder.

### **JURISDICTION AND VENUE**

2. The claims asserted herein arise under and pursuant to §§10(b) and 20(a) of the Exchange Act (15 U.S.C. §§78j(b) and §78t(a)) and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §240.10b-5).

3. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §1331 and §27 of the Exchange Act.

4. Venue is proper in this District pursuant to §27 of the Exchange Act (15 U.S.C. §78aa) and 28 U.S.C. §1391(b) as the Company conducts business and a significant portion of the Defendants’ actions, and the subsequent damages, took place within this District.

5. In connection with the acts, conduct and other wrongs alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including but not limited to, the United States mail, interstate telephone communications and the facilities of the national securities exchange.

## PARTIES

6. Plaintiff, as set forth in the accompanying Certification, purchased Roche securities at artificially inflated prices during the Class Period and was damaged upon the revelation of the alleged corrective disclosure.

7. Defendant Roche is a Switzerland corporation with its principal place executive offices located at Konzern Hauptsitz Grenzacherstrasse 124, CH-4070 Basel, Schweiz. Roche operates in the pharmaceuticals and diagnostics businesses worldwide. The Company's subsidiary, Roche Molecular Systems Inc., maintains offices at Building 500, 1080 U.S. Highway 202, Branchburg, NJ 08876. The Company trades on the OTCQX Marketplace under the ticker symbol "RHHBY."

8. Defendant Severin Schwan ("Schwan") has been Chief Executive Officer ("CEO") of Roche since March 2008.

9. Defendant Alan Hippe ("Hippe") has been the Chief Financial & IT Officer at Roche since April 2011.

10. Defendants Schwan and Hippe are sometimes referred to herein as the "Individual Defendants."

11. Each of the Individual Defendants:

- (a) directly participated in the management of the Company;
- (b) was directly involved in the day-to-day operations of the Company at the highest levels;
- (c) was privy to confidential proprietary information concerning the Company and its business and operations;

- (d) was directly or indirectly involved in drafting, producing, reviewing and/or disseminating the false and misleading statements and information alleged herein;
- (e) was directly or indirectly involved in the oversight or implementation of the Company's internal controls;
- (f) was aware of or recklessly disregarded the fact that the false and misleading statements were being issued concerning the Company; and/or
- (g) approved or ratified these statements in violation of the federal securities laws.

12. The Company is liable for the acts of the Individual Defendants and its employees under the doctrine of *respondeat superior* and common law principles of agency because all of the wrongful acts complained of herein were carried out within the scope of their employment.

13. The scienter of the Individual Defendants and other employees and agents of the Company is similarly imputed to the Company under *respondeat superior* and agency principles.

14. The Company and the Individual Defendants are referred to herein, collectively, as the "Defendants."

## **SUBSTANTIVE ALLEGATIONS**

### **Background**

15. Herceptin (trastuzumab) is indicated for the treatment of HER2-positive breast cancer and HER2-positive metastatic gastric cancer.

16. Perjeta is a personalized medicine approved by the U.S. Food and Drug Administration and European Commission in combination with Herceptin for the treatment of patients with previously untreated HER2-positive metastatic breast cancer.

## Materially False and Misleading Statements

17. On March 2, 2017, Roche issued a release entitled, “Phase III APHINITY study shows Roche’s Perjeta® regimen helped people with an aggressive type of early breast cancer live longer without their disease returning compared to Herceptin® and chemotherapy,” stating in pertinent part:

Basel, 02 March 2017

### **Phase III APHINITY study shows Roche’s Perjeta® regimen helped people with an aggressive type of early breast cancer live longer without their disease returning compared to Herceptin® and chemotherapy**

- Perjeta plus Herceptin and chemotherapy showed a statistically significant improvement in invasive disease-free survival (iDFS) for people with HER2-positive early breast cancer (eBC) compared to Herceptin and chemotherapy alone
- Data will be discussed with health authorities, including the US Food and Drug Administration (FDA) and European Medicines Agency (EMA)

Roche (SIX: RO, ROG; OTCQX: RHHBY), the Breast International Group (BIG), Breast European Adjuvant Study Team (BrEAST) and Frontier Science Foundation (FS) today announced positive results from the phase III APHINITY study. The study met its primary endpoint and showed that adjuvant (after surgery) treatment with the combination of Perjeta® (pertuzumab), Herceptin® (trastuzumab) and chemotherapy (the Perjeta-based regimen) achieved a statistically significant reduction in the risk of recurrence of invasive disease or death (invasive disease-free survival; iDFS) in people with HER2-positive early breast cancer (eBC) compared to Herceptin and chemotherapy alone. The safety profile of the Perjeta-based regimen was consistent with that seen in previous studies<sup>1</sup>, and no new safety signals were identified. Full results from the APHINITY trial will be presented at an upcoming medical meeting in 2017.

“These results from the positive APHINITY study represent an important addition to the body of data for Perjeta in the treatment of people with HER2-positive early breast cancer,” said Sandra Horning, MD, Chief Medical Officer and Head of Global Product Development at Roche. “We look forward to discussing these adjuvant results with global regulatory authorities.”

Gunter von Minckwitz, MD, study coordinator from the Breast International Group and academic study partners, added, “APHINITY provides yet another

example of the importance of industry-academic collaborations and their value in advancing cancer care for people affected by this challenging disease.”

HER2-positive breast cancer is an aggressive form of the disease, which affects approximately one in five people with breast cancer<sup>2</sup> and is associated with a poor prognosis if left untreated.<sup>3</sup> Despite advancements in the treatment of HER2-positive eBC, up to one in three people treated with Herceptin and chemotherapy may eventually see their cancer return.<sup>4,5</sup> Treatment options are needed to improve the outcomes of people with this aggressive disease. Treating breast cancer early, before it has spread, may improve the chance of preventing the disease from returning and potentially reaching an incurable stage.<sup>6</sup> Adjuvant therapy is given after surgery and is aimed at killing any remaining cancer cells to reduce the risk of the cancer returning.<sup>6</sup>

The combination of Perjeta, Herceptin and chemotherapy is licenced as a neoadjuvant (before surgery) treatment for people with HER2-positive eBC in more than 75 countries worldwide following approvals by the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA).<sup>1,7</sup> In the US, the regimen is currently available under the FDA accelerated approval programme. The APHINITY trial reflects the commitment to evaluate the Perjeta-based regimen as part of a complete treatment approach for eBC. These data will be discussed with health authorities across the world, including the US FDA with the hope to convert the current US accelerated approval to a full approval.

18. The statements referenced in ¶ 17 above were materially false and/or misleading because they misrepresented and failed to disclose the following adverse facts pertaining to the Company’s business, operational and financial results, which were known to Defendants or recklessly disregarded by them. Specifically, Defendants made false and/or misleading statements and/or failed to disclose that: (1) the combination of Perjeta and Herceptin is only marginally more effective than Herceptin alone in preventing breast cancer; and (2) as a result, Defendants’ statements about the Company’s business, operations and prospects were materially false and misleading and/or lacked a reasonable bases at all relevant times.

## **The Truth Emerges**

19. On June 5, 2017, Roche issued a release entitled, “APHINITY study shows Roche’s Perjeta-based regimen reduced the risk of invasive cancer returning compared to Herceptin and chemotherapy in HER2-positive early breast cancer,” stating in pertinent part:

Basel, 05 June 2017

### **APHINITY study shows Roche’s Perjeta-based regimen reduced the risk of invasive cancer returning compared to Herceptin and chemotherapy in HER2-positive early breast cancer**

- **Phase III study confirms benefit of the Perjeta-based regimen over the current standard of care**
- **The study was positive in the overall population, with greatest risk reduction in patients with node-positive or hormone receptor-negative disease**
- **Data will be submitted to global health authorities**

Roche (SIX: RO, ROG; OTCQX: RHHBY), the Breast International Group (BIG), Breast European Adjuvant Study Team (BrEAST) and Frontier Science Foundation (FS) today announced the Phase III APHINITY study showed adjuvant (after surgery) treatment with the combination of Perjeta® (pertuzumab), Herceptin® (trastuzumab) and chemotherapy (the Perjeta-based regimen) significantly reduced the risk of breast cancer recurrence or death (invasive disease-free survival; iDFS) by 19% in people with HER2-positive early breast cancer (eBC) compared to Herceptin and chemotherapy alone (HR=0.81; 95% CI 0.66-1.00, p=0.045).<sup>1</sup> At three years, 94.1% of people treated with the Perjeta-based regimen did not have their breast cancer return compared to 93.2% treated with Herceptin and chemotherapy.<sup>1</sup> The safety profile of the Perjeta-based regimen was consistent with that seen in previous studies, with a low incidence of cardiac events and no new safety signals.<sup>1,2</sup>

Based on data available at the time of the primary analysis, an estimate of iDFS at four years showed that 92.3% of people treated with the Perjeta-based regimen did not have their breast cancer return compared to 90.6% treated with Herceptin and chemotherapy, suggesting that further analyses with longer follow-up will be important to provide additional insights on these treatments.<sup>1</sup>

“The goal of adjuvant treatment is to help each person with cancer have the best chance of a cure, and we come closer to this goal with each advance,” said Sandra Horning, M.D., Chief Medical Officer and Head of Global Product Development. “In the APHINITY study, the Perjeta-based regimen improved upon the high bar

set by Herceptin in people with HER2-positive early breast cancer. We look forward to working with global health authorities to bring this treatment option to patients.”

Gunter von Minckwitz, M.D., study coordinator from the BIG and academic study partners, President of the German Breast Group, added, “APHINITY provides yet another example of the importance of industry-academic collaborations and their value in advancing cancer care for people affected by this challenging disease. The median follow-up at the primary analysis was 45.4 months, and these early data are very encouraging. As we continue to follow patients up to 10 years, we hope that future analyses will provide additional insights on the role of a pertuzumab-based regimen in HER2-positive early breast cancer.”

At the time of the primary analysis, with median follow-up of 45.4 months, the reduction in risk of invasive breast cancer recurrence with the Perjeta-based regimen was greatest in people with lymph node-positive (HR=0.77; 95% CI 0.62-0.96, p=0.019) or hormone receptor-negative disease (HR=0.76; 95% CI 0.56-1.04, p=0.085).<sup>1</sup> At three years, among people with node-positive disease, 92.0% of people treated with the Perjeta-based regimen did not have their breast cancer return compared to 90.2% treated with Herceptin and chemotherapy, and iDFS rates in the hormone receptor-negative disease subgroup were 92.8% in the Perjeta-based arm and 91.2% in the Herceptin and chemotherapy arm.<sup>1</sup> The number of events in both treatment arms was low in people with node-negative disease, where no benefit with the Perjeta-based regimen was detected at this time.<sup>1</sup>

HER2-positive breast cancer is an aggressive form of the disease that affects approximately one in five people with breast cancer.<sup>3</sup> Despite advancements in the treatment of HER2-positive eBC, one in four people treated with Herceptin and chemotherapy will eventually see their cancer return in the long-term.<sup>4,5</sup> Treating breast cancer early, before it has spread, may help prevent the disease from returning and potentially reaching an incurable stage.<sup>6</sup> Adjuvant therapy is given after surgery and is aimed at killing any remaining cancer cells to help reduce the risk of the cancer returning.<sup>6</sup>

Full results of the primary analysis will be presented in an oral session today at the 53<sup>rd</sup> Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago by Gunter von Minckwitz, M.D., study coordinator from the BIG and academic study partners (Abstract #LBA500), and will be featured in ASCO’s official press programme. Results from the APHINITY trial will also be published today in the *New England Journal of Medicine*.



20. On June 5, 2017, *Financial Times* published an article entitled, “Roche suffers blow over breast cancer combination therapy,” stating that as a result of Roche’s trial results showing only a marginal benefit from using Roche’s new combination of Herceptin and Perjeta to combat breast cancer, oncologists might refrain from using the combination not only for cost reasons, but because Perjeta causes severe diarrhea in some patients, stating in pertinent part:

**Roche suffers blow over breast cancer combination therapy**

**Large trial shows only marginal benefit from taking cocktail of Herceptin and Perjeta**

10 HOURS AGO by: David Crow in Chicago

Roche’s hopes of protecting its \$7bn breast cancer franchise with a new drug cocktail were dealt a blow after a large trial showed the combination was only marginally better than an older medicine made by the company.

The Swiss pharmaceuticals group had hoped to defend itself against the launch of a copycat version of its blockbuster breast cancer medicine, Herceptin, by combining the drug with one of its newer drugs, Perjeta.

The clinical trial showed the two medicines were better than one at stopping cancer returning after surgery, but that the benefit was slight.

After three years, 94.1 per cent of patients taking the cocktail were disease-free, versus 93.2 per cent of those on Herceptin alone, according to the data, which were presented at the world’s largest cancer meeting on Monday.

Roche has already secured regulatory approval for the combination in some breast cancer sufferers, but oncologists could decide to stick to the single drug for the majority of patients after seeing the data.

“The trial tells us the combo is better than the single regimen, but that the difference is small,” said Dr Daniel Hayes, president of the American Society of Clinical Oncology, which is organising the conference in Chicago.

Herceptin and Perjeta each cost about \$70,000 for a year of treatment and the drugs generated a combined SFr8.6bn (\$8.9bn) in sales for Roche last year.

But the patents protecting Herceptin have expired, and Mylan, a generic drugs company, in March reached an agreement with Roche that would allow it to start selling a cut-price “biosimilar” version of the medicine in large markets.

Analysts expect Roche to counter the copycat threat by touting the benefits of the newer cocktail therapy, which is sold in a combination pack.

Dr Hayes said oncologists might refrain from using the new combination not just for cost reasons, but also because Perjeta causes severe diarrhoea in some patients.

In the clinical trial, roughly one in 10 patients experienced grade three diarrhoea, which means a person can struggle to control their bowel movements and may need to be treated in a hospital or clinic.

However, Dr Hayes said he thought some people might be good candidates for the combo, and that more studies needed to be done to work out those most likely to benefit.

“I hope we’ll be thoughtful about how we use Perjeta — without causing unnecessary diarrhoea, and without breaking the bank,” he said.

Before the data were published on Monday, one large Roche investor said there was “a lot of nervousness” among shareholders over the outcome of the trial.

“The big question is whether the data are enough to convince clinicians that the standard of care in HER2 positive breast cancer is now the Herceptin and Perjeta combination,” said analysts at HSBC.

21. On June 5, 2017, *Bloomberg Quint* published an article entitled, “Roche's Pricey New Breast-Cancer Combo Barely Beats Old Drug,” that Roche’s results won’t justify moving a majority of patients to Roche’s pricey new combo treatment, stating in pertinent part:

**Roche's Pricey New Breast-Cancer Combo Barely Beats Old Drug**

by Naomi Kresge Michelle Fay Cortez

Updated on June 5, 2017, 12:33 pm

Published on June 5, 2017, 7:55 am

(Bloomberg) -- Roche Holding AG’s new breast cancer combination therapy barely outperformed a current gold-standard drug for the disease -- the company’s own decades-old Herceptin -- in its latest study.

The results, presented Monday in Chicago at the world's largest gathering of cancer researchers, are a disappointment and probably won't justify moving a majority of patients to Roche's pricey new combo treatment, doctors say. Researchers had warned that it would be tough to top Herceptin, which revolutionized treatment for women with an aggressive type of breast cancer called HER2-positive after Roche introduced it in 1998.

The U.S. shares of the Swiss drugmaker slumped as much as 8.1 percent in New York, the biggest drop since April 2009. There's no trading in Zurich on Monday because of a public holiday.

Adding Roche's new medicine Perjeta to Herceptin -- which could double the current monthly cost of \$6,100 -- resulted in about 1 percentage point of improvement in the proportion of women who lived at least three years without tumors returning. For patients with less severe cancer, where tumors hadn't spread to the lymph nodes, Perjeta didn't help at all.

"There are going to be people who look at the presentation and are a little disappointed that the benefits aren't greater," said Eric Winer, director of the Breast Oncology Center at the Dana-Farber Cancer Institute in Boston. "On the other hand, for those people who thought about it carefully, this is probably not very surprising."

The late-stage results presented at the American Society of Clinical Oncology's annual meeting come at a critical time for the Swiss giant, which faces the first competition from cheaper copies of Herceptin as early as this year.

Shares of rival Puma Biotechnology Inc. jumped 11 percent to \$90.70. The underwhelming Roche data could benefit Puma, which also has an experimental drug used in addition to Herceptin. The U.S. Food and Drug Administration will decide on the Puma medication in July, after an advisory panel recommended its approval last month.

### **Goal is Cure**

Roche officials welcomed its combo results, saying women with higher-risk tumors, including those that had spread to the lymph nodes or wouldn't respond to hormone therapy, derived the most benefit. The goal of treatment is a cure, and reducing the development of invasive disease would give thousands more a shot at a cancer-free life, said Sandra Horning, Roche's chief medical officer.

"We are talking about life-and-death issues in the early breast-cancer setting," she said.

Harold Burstein, an associate professor of medicine at Harvard Medical School and institute physician at Dana Farber, agreed that the combination therapy will

be valuable in higher-risk patients. He estimated that as many as 25,000 of the 250,000 people diagnosed with breast cancer in the U.S. each year might benefit.

### **‘Needs More Time’**

The initial benefit seen in the trial increased over time, according to Gunter von Minckwitz, lead researcher on the Roche study.

“To have a full assessment not only on the long-term effect but also on long-term safety, this is just something that needs more time,” said von Minckwitz, who is president of the German Breast Group in Neu-Isenburg. “It is reasonable to give this to patients.”

One in four women taking Herceptin eventually developed a recurrence in an older test, so reducing the risk of relapsing is critical, said Daniel O’Day, head of Roche’s head of pharmaceuticals. The company plans to track the women for years to determine if the improvement continues to increase over time.

### **‘A Disappointment’**

Still, an editorial in the New England Journal of Medicine, where the results of the study were simultaneously published, rejected the idea that a longer follow-up could lead to a very different result. It also concluded that the improvement from adding Perjeta was “a disappointment” compared with the benefits seen before surgery or for women with advanced disease. What’s more, it said the investigators didn’t properly analyze the drug’s potential effect on the heart in the trial.

The researchers followed 4,805 women who had already had surgery for early breast cancer, randomly assigning them to receive the current standard of chemotherapy plus a year of Herceptin, or chemotherapy plus a year of Herceptin and Perjeta. After three years, 94.1 percent of the patients on the new combo hadn’t developed invasive breast cancer, compared with 93.2 percent of the Herceptin-only patients.

The benefit was bigger for patients whose cancer had spread to lymph nodes: 92 percent of those who got Perjeta were free of invasive disease at the three-year mark, compared with 90.2 percent of those who received only Herceptin.

Meanwhile, 9.8 percent of patients on the Perjeta combination suffered from severe diarrhea, compared with 3.7 percent for those who only took Herceptin.

“The toxic effects (and costs) are too great for too many to benefit too few,” Kathy Miller, a professor of oncology at the Indiana University Cancer Center in Indianapolis, wrote in the New England Journal of Medicine editorial. “Trials that

involve patients at low risk should do less, seeking to eliminate toxic effects for patients who are likely to do well.”

At stake for Roche are billions of dollars: Herceptin brought in about \$7 billion in sales last year, about 13 percent of total revenue at the Basel, Switzerland-based company. Analysts are projecting the drug’s sales to decline over the next years, but combined revenue with Perjeta is seen rising to more than \$10 billion in 2020.

22. On June 5, 2017, Fox Business published an article entitled, “Study Questions Value of Costly Cancer-Drug Combinations,” citing the concerns of medical professionals regarding Roche’s trial results of its Herceptin/Perjeta drug combination, stating in pertinent part:

#### **Study Questions Value of Costly Cancer-Drug Combinations**

By Peter Loftus Published June 05, 2017 **Features** Dow Jones Newswires

CHICAGO – A new study is stirring debate about whether the benefits of cancer drugs are worth their cost, particularly as drugmakers develop treatments that combine multiple pricey drugs.

The study of about 4,800 women with an aggressive type of breast cancer found that adding Roche Holding AG's drug Perjeta to the company's older treatment Herceptin conferred a slight benefit versus Herceptin alone, after the women had undergone surgery to remove tumors. Some 94.1% of women receiving the combination in the study stayed free of invasive breast cancer three years after the start of treatment, versus 93.2% of those who received Herceptin alone -- a difference of less than a percentage point.

That modest benefit comes at a high price: more than doubling the one-year treatment cost to \$158,000 a patient from \$74,500. The combination also had higher rates of certain side effects than Herceptin alone, including severe diarrhea.

"The marginal improvement of adding Perjeta is tiny for the average person, but the incremental cost is going to be substantial," said Richard Schilsky, chief medical officer of the American Society of Clinical Oncology, which is hosting a conference where the study results were released Monday. He wasn't involved in the study.

Dr. Kathy D. Miller, an oncologist at Indiana University Melvin and Bren Simon Cancer Center in Indianapolis, wrote a critical editorial in the New England

Journal of Medicine, published online along with the study results Monday. "The toxic effects (and cost) are too great for too many to benefit too few," she wrote.

Roche said the benefit of Perjeta and Herceptin in the new study could mean the difference between relapse and staying disease-free for many women. "We see this as a very meaningful benefit," Daniel O'Day, CEO of Roche's pharmaceutical unit, said in an interview. The company plans to file for regulatory approval to market the combination for patients after breast-cancer surgery, also known as adjuvant treatment.

The finding comes as many drug companies including Roche, Merck & Co. and AstraZeneca PLC race to test whether new combinations of cancer drugs can improve outcomes versus single-drug therapy or older treatments.

Last month, the Food and Drug Administration approved adding Merck & Co.'s Keytruda, which costs \$13,000 a month, to an older combination of lung-cancer treatments that includes Eli Lilly & Co.'s Alimta, which costs more than \$5,700 for a 21-day treatment cycle.

In 2015, the FDA approved the use of a combination of Bristol-Myers Squibb Co.'s Yervoy and Opdivo to treat the deadly skin cancer melanoma, based on a study showing it slowed cancer progression better than either drug alone. The two drugs together cost more than \$250,000 for the first full year of treatment.

For one class of cancer drugs, which harness the body's immune system to attack tumors, the number of clinical trials testing them in combination with other drugs more than tripled to 765 from 215 in late 2015, according to a new report from industry research firm Evaluate Ltd. Roche alone is running 45 clinical trials that test combinations of cancer immunotherapies, said Sandra Horning, chief medical officer of Roche's Genentech unit.

The trend concerns health insurers. UnitedHealth Group sometimes has to pay much more for the use of cancer combination therapies that contain pricey new brand-name drugs than it does for cheaper combinations of generic drugs that may be just as good, Lee Newcomer, senior vice president of oncology and genetics, said at a panel discussion about cost at the ASCO conference.

In the study, the Perjeta-Herceptin combination had a more pronounced benefit in a subset of women considered at higher risk of relapse, including those with cancer that had spread to lymph nodes, Gunter von Minckwitz, lead researcher for the study and head of the German Breast Group, an academic alliance that runs clinical trials, said in an interview. He said he expects health insurers and government health programs to be more open to paying for the combination's use in higher-risk patients.

Some doctors said they would probably avoid using the Perjeta-Herceptin combination in patients at lower risk of relapse. "Would I have preferred to see a higher benefit? Certainly yes," Eleni Andreopoulou, a breast-cancer specialist at Weill Cornell Medicine and NewYork-Presbyterian hospital, said in an interview. Dr. Andreopoulou, who enrolled patients in the study but wasn't a lead researcher, called it a positive result but said she would like to see more tests developed to predict which patients are more likely to benefit from the combination based on biological traits of tumors, and which aren't.

Herceptin, introduced in 1998, improved treatment of breast tumors with high levels of the protein HER2, particularly after surgery. Roche introduced Perjeta in 2012 to be used in combination with Herceptin to try for an even greater benefit.

Regulators previously approved the Herceptin-Perjeta combination to treat HER2-positive breast cancer at earlier and later stages of development than the one in the new study: cancers that have spread to other parts of the body, and cancers before women undergo surgery.

Roche reported about \$7 billion in global Herceptin sales last year, and about \$1.9 billion in Perjeta sales.

23. On this news, shares of Roche fell \$1.76 per share or approximately 5.12% from its previous closing price to close at \$32.61 per share on June 5, 2017, damaging investors.

24. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of the Company's securities, Plaintiff and other Class members have suffered significant losses and damages.

### **PLAINTIFF'S CLASS ACTION ALLEGATIONS**

25. Plaintiff brings this action as a class action pursuant to Federal Rule of Civil Procedure 23(a) and (b)(3) on behalf of a Class, consisting of all those who purchased or otherwise acquired the publicly traded securities of Roche during the Class Period (the "Class"); and were damaged upon the revelation of the alleged corrective disclosure. Excluded from the Class are Defendants herein, the officers and directors of the Company, at all relevant times,

members of their immediate families and their legal representatives, heirs, successors or assigns and any entity in which Defendants have or had a controlling interest.

26. The members of the Class are so numerous that joinder of all members is impracticable. Throughout the Class Period, the Company's securities were actively traded on the OTCQX Marketplace. While the exact number of Class members is unknown to Plaintiff at this time and can be ascertained only through appropriate discovery, Plaintiff believes that there are hundreds or thousands of members in the proposed Class. Record owners and other members of the Class may be identified from records maintained by the Company or its transfer agent and may be notified of the pendency of this action by mail, using the form of notice similar to that customarily used in securities class actions.

27. Plaintiff's claims are typical of the claims of the members of the Class as all members of the Class are similarly affected by Defendants' wrongful conduct in violation of federal law that is complained of herein.

28. Plaintiff will fairly and adequately protect the interests of the members of the Class and has retained counsel competent and experienced in class and securities litigation. Plaintiff has no interests antagonistic to or in conflict with those of the Class.

29. Common questions of law and fact exist as to all members of the Class and predominate over any questions solely affecting individual members of the Class. Among the questions of law and fact common to the Class are:

- a. whether Defendants' acts as alleged violated the federal securities laws;
- b. whether Defendants' statements to the investing public during the Class Period misrepresented material facts about the financial condition, business, operations, and management of the Company;



- c. whether Defendants' statements to the investing public during the Class Period omitted material facts necessary to make the statements made, in light of the circumstances under which they were made, not misleading;
- d. whether the Individual Defendants caused the Company to issue false and misleading SEC filings and public statements during the Class Period;
- e. whether Defendants acted knowingly or recklessly in issuing false and misleading SEC filings and public statements during the Class Period;
- f. whether the prices of the Company's securities during the Class Period were artificially inflated because of the Defendants' conduct complained of herein; and
- g. whether the members of the Class have sustained damages and, if so, what is the proper measure of damages.

30. A class action is superior to all other available methods for the fair and efficient adjudication of this controversy since joinder of all members is impracticable. Furthermore, as the damages suffered by individual Class members may be relatively small, the expense and burden of individual litigation make it impossible for members of the Class to individually redress the wrongs done to them. There will be no difficulty in the management of this action as a class action.

31. Plaintiff will rely, in part, upon the presumption of reliance established by the fraud-on-the-market doctrine in that:

- a. Defendants made public misrepresentations or failed to disclose material facts during the Class Period;
- b. the omissions and misrepresentations were material;
- c. the Company's securities are traded in efficient markets;

- d. the Company's securities were liquid and traded with moderate to heavy volume during the Class Period;
- e. the Company traded on the OTCQX Marketplace, and was covered by multiple analysts;
- f. the misrepresentations and omissions alleged would tend to induce a reasonable investor to misjudge the value of the Company's securities;
- g. Plaintiff and members of the Class purchased and/or sold the Company's securities between the time the Defendants failed to disclose or misrepresented material facts and the time the true facts were disclosed, without knowledge of the omitted or misrepresented facts; and
- h. Unexpected material news about the Company was rapidly reflected in and incorporated into the Company's stock price during the Class Period.

32. Based upon the foregoing, Plaintiff and the members of the Class are entitled to a presumption of reliance upon the integrity of the market.

33. Alternatively, Plaintiff and the members of the Class are entitled to the presumption of reliance established by the Supreme Court in *Affiliated Ute Citizens of the State of Utah v. United States*, 406 U.S. 128, 92 S. Ct. 2430 (1972), as Defendants omitted material information in their Class Period statements in violation of a duty to disclose such information, as detailed above.

### **COUNT I**

#### **Violation of Section 10(b) of The Exchange Act and Rule 10b-5 Against All Defendants**

34. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

35. This Count is asserted against the Company and the Individual Defendants and is based upon Section 10(b) of the Exchange Act, 15 U.S.C. § 78j(b), and Rule 10b-5 promulgated thereunder by the SEC.

36. During the Class Period, the Company and the Individual Defendants, individually and in concert, directly or indirectly, disseminated or approved the false statements specified above, which they knew or deliberately disregarded were misleading in that they contained misrepresentations and failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading.

37. The Company and the Individual Defendants violated §10(b) of the 1934 Act and Rule 10b-5 in that they: employed devices, schemes and artifices to defraud; made untrue statements of material facts or omitted to state material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; or engaged in acts, practices and a course of business that operated as a fraud or deceit upon plaintiff and others similarly situated in connection with their purchases of the Company's securities during the Class Period.

38. The Company and the Individual Defendants acted with scienter in that they knew that the public documents and statements issued or disseminated in the name of the Company were materially false and misleading; knew that such statements or documents would be issued or disseminated to the investing public; and knowingly and substantially participated, or acquiesced in the issuance or dissemination of such statements or documents as primary violations of the securities laws. These defendants by virtue of their receipt of information reflecting the true facts of the Company, their control over, and/or receipt and/or modification of the Company's allegedly materially misleading statements, and/or their associations with the

Company which made them privy to confidential proprietary information concerning the Company, participated in the fraudulent scheme alleged herein.

39. Individual Defendants, who are the senior officers and/or directors of the Company, had actual knowledge of the material omissions and/or the falsity of the material statements set forth above, and intended to deceive Plaintiff and the other members of the Class, or, in the alternative, acted with reckless disregard for the truth when they failed to ascertain and disclose the true facts in the statements made by them or other personnel of the Company to members of the investing public, including Plaintiff and the Class.

40. As a result of the foregoing, the market price of the Company's securities were artificially inflated during the Class Period. In ignorance of the falsity of the Company's and the Individual Defendants' statements, Plaintiff and the other members of the Class relied on the statements described above and/or the integrity of the market price of the Company's securities during the Class Period in purchasing the Company's securities at prices that were artificially inflated as a result of the Company's and the Individual Defendants' false and misleading statements.

41. Had Plaintiff and the other members of the Class been aware that the market price of the Company's securities had been artificially and falsely inflated by the Company's and the Individual Defendants' misleading statements and by the material adverse information which the Company and the Individual Defendants did not disclose, they would not have purchased the Company's securities at the artificially inflated prices that they did, or at all.

42. As a result of the wrongful conduct alleged herein, Plaintiff and other members of the Class have suffered damages in an amount to be established at trial.

43. By reason of the foregoing, the Company and the Individual Defendants have violated Section 10(b) of the 1934 Act and Rule 10b-5 promulgated thereunder and are liable to the Plaintiff and the other members of the Class for substantial damages which they suffered in connection with their purchases of the Company's securities during the Class Period.

## **COUNT II**

### **Violation of Section 20(a) of The Exchange Act Against The Individual Defendants**

44. Plaintiff repeats and realleges each and every allegation contained in the foregoing paragraphs as if fully set forth herein.

45. During the Class Period, the Individual Defendants participated in the operation and management of the Company, and conducted and participated, directly and indirectly, in the conduct of the Company's business affairs. Because of their senior positions, they knew the adverse non-public information regarding the Company's business practices.

46. As officers and/or directors of a publicly owned company, the Individual Defendants had a duty to disseminate accurate and truthful information with respect to the Company's financial condition and results of operations, and to correct promptly any public statements issued by the Company which had become materially false or misleading.

47. Because of their positions of control and authority as senior officers, the Individual Defendants were able to, and did, control the contents of the various reports, press releases and public filings which the Company disseminated in the marketplace during the Class Period. Throughout the Class Period, the Individual Defendants exercised their power and authority to cause the Company to engage in the wrongful acts complained of herein. The Individual Defendants therefore, were "controlling persons" of the Company within the meaning

of Section 20(a) of the Exchange Act. In this capacity, they participated in the unlawful conduct alleged which artificially inflated the market price of the Company's securities.

48. Each of the Individual Defendants, therefore, acted as a controlling person of the Company. By reason of their senior management positions and/or being directors of the Company, each of the Individual Defendants had the power to direct the actions of, and exercised the same to cause, the Company to engage in the unlawful acts and conduct complained of herein. Each of the Individual Defendants exercised control over the general operations of the Company and possessed the power to control the specific activities which comprise the primary violations about which Plaintiff and the other members of the Class complaint.

49. By reason of the above conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act for the violations committed by the Company.

#### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Plaintiff and the Class by reason of the acts and transactions alleged herein;

C. Awarding Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees and other costs; and

D. Awarding such other and further relief as this Court may deem just and proper.

#### **DEMAND FOR TRIAL BY JURY**

Plaintiff hereby demands a trial by jury.